

### REMARKS

This amendment is being filed in reply to the office action of October 16, 2002, a reply to which was due without request for extension of time by January 16, 2003, and a reply to which is due with the accompanying request for One Month Extension of Time under 37 CFR §1.136 by February 17, 2003.

All of the claims under rejection have been replaced by claims 61-85, the language of which is respectfully submitted to overcome the following objections and rejections propounded by the Examiner in charge of the above-identified application at ¶¶1 and 2 on page 2 of the October 16, 2002 Office Action:

- The withdrawal of claims 56, 59 and 60 (now replaced, respectively by the newly-presented claims 83, 84 and 85) for being directed to an invention that lacks unity with the invention originally claimed;
- The objections to claims 40, 42, 46, 51, 52 and 53 (now replaced by the newly-presented independent claims 67, 69, 73, 78, 79 and 80, respectively) for depending on rejected claims; and
- The rejection of claims 43 (now replaced by newly-presented claim 70) and claim 57 (cancelled herein without replacement) under 35 USC §112.

It is respectfully pointed out to the Examiner in Charge of the above-identified application that the newly presented claims which include additional limitations are not rejectable based on "new matter" under 35 USC §132. Thus, with reference to the newly presented claims 72 and 73, replacing claims 45 and 46, an additional group of

diols has been added; and basis for this amendment exists at page 7 lines 12-14 of the specification as filed. Basis for the newly presented claim 62 is found at page 5, line 32. Basis for newly-presented claim 63 is to be found at page 5, line 34 to page 6, line 1 and page 7, lines 10-19. The claim language concerning the requirement of at least 90% uniform block length in newly presented claims 71 and 83 has basis at line 8, page 7 of the specification as filed.

With reference to claim 83 (replacing previously-presented claim 56), it is now specified that 90% of the diol units have the same length. The YXY product may be synthesized as indicated at page 5, lines 17-22 of the specification. The YXY may serve as a chain extender that reacts with the prepolymer. The YXY, itself, is not a prepolymer. The product YXYXY may be synthesized as indicated at page 7, lines 15-18 and may also serve as a chain extender. Both YXY and YXYXY are novel intermediate products suitable for use in synthesizing a polyurethane according to Applicants' invention. Accordingly, the invention defined in claim 83 is the same invention as defined in the remaining claims 61-82, as newly presented.

With reference to claims 84 and 85 (replacing previously-presented claims 59 and 60) claims 84 and 85 are now dependent and limited to the subject matter defined according to newly-presented claim 61, thereby obviated any objection based on lack of unity.

In both claims 79 (which replaced claim 43) and claims 79 and 80 (which replaced claims 52 and 53) the term "based on number" has been replaced by --based on the total number of monomeric units in the polymer--. It is well

within the skill and knowledge of one having ordinary skill in the art of polymer technology that a percentage based on number is based on the total number of repeating monomeric units in a polymer...and not on the total molecular weight or average weight of the polymer. Thus the term "based on number" is a term that is intended to fully clarify the meaning of the claim language in conformity with 35 USC 112.

Previously-presented claims 40, 42, 46, 51, 52 and 53 were objected to in ¶15 on page 5 of the October 16, 2002 Office Action as depending on rejected claims. These claims have been replaced by newly-presented independent claims 67, 69, 73, 78, 79 and 80, respectively. The objection having been overcome, claims 67, 69, 73, 79 and 80 are respectfully submitted to be allowable.

With reference to the arguments presented *infra*, regarding the 35 USC §§102 and 103 rejections discussed *infra*, it is herewith respectfully pointed out to the Examiner in Charge of the above-identified application that the presented invention relates to a biomedical biocompatible biodegradable polyurethane based on a diisocyanate-linked polyester polymer and a diol component, said polyurethane having the formula:  $\{A-B-C-B\}_n$ , wherein A denotes the polyester component, B denotes the diisocyanate moiety, C denotes the diol component, *n* denotes the number of recurring units, and wherein the block length is the same for at least 90% of the diol units. The high level of uniformity contributes to a phase separation during the processing of the polymer as the uniform segments crystallize and form strong hydrogen bonds with other uniform segments thereby resulting in physical cross-links. As a result, the polymer of Applicants' invention is

unexpectedly, unobviously and advantageously suitable to produce a biocompatible, biodegradable implant with excellent unforeseeable mechanical properties; and a substantial need, exists in the international medical practice for such a polymer.

In ¶¶4-6 on page 3 of the Office Action of October 16, the Examiner in charge of the above-identified application rejected claim 44 as being anticipated by Ambrose et al (U.S. Patent 4,543,405) and claims 34, 35, 38, 45, 49, 50, 54 as being anticipated by Quay (U.S. Patent 4,892,920) under 35 USC §102(b).

In ¶¶7-14 on pages 3-5 of the Office Action of October 16, 2002, claims ~~34-39~~ 41, 45, 47-49, 54 and 55 (herein replaced by claims ~~61-66~~ 68, 72, 74-76, 81 and 82) were rejected under 35 USC §103(a) as unpatentable over de Groot et al ("New biomedical...") in view of Cohn et al (U.S. Patent 5,100,992), de Groot ("Use of porous...") and Gogolewski (U.S. Patent 4,915,893).

Claim 44 has now been replaced by claim 71. Claims 34, 35, ~~38~~ 45, 49, 50 and 54 have now been replaced by claims 61, 62, ~~63~~ 72, 76, 77 and 81.

With respect to the rejection of claim 44 (now replaced by claim 71), the uniformity of the block length "for at least 90% of the diol components" is neither expressly or implicitly present in the Ambrose et al reference. Furthermore, there is no suggestion in the Ambrose et al reference to combine the 1,4-butane diisocyanate with any of the diols as set forth in newly-presented claim 71. Indeed the Ambrose et al

reference teaches away from the invention defined according to claim 71 to wit: the 1,4-butane diisocyanate is not set forth as a preferred component but is merely part of a 'shotgun' disclosure at Column 6, line 41 of Ambrose et al. Each of the Examples of Ambrose et al at Columns 10-14 set forth the use of a diisocyanate (to wit: e.g., trimethylhexamethylene diisocyanate) different in kind rather than degree from the 1,4-butane diisocyanate of claim 71. Nothing in the Ambrose et al reference even remotely suggests that such a combination would give rise to a good building block for a chain extender for preparing a polyurethane having the necessary mechanical properties required, e.g., for a biomedical implant.

With respect to the rejection of claims 34, 35, 38, 45, 49, 50 and 54 (now replaced by claims 61, 62, 63, 73, 76, 77 and 81) over Quay et al, it is respectfully urged that the rejection over the Quay reference is in error. Quay et al describes a polyisocyanate prepolymer for polyurethane/urea elastomer synthesis. The prepolymer is formed by reacting a cyclohexane diisocyanate and a long chain polyol. It follows, from a reading of the Quay et al examples at Columns 6-11 that those prepolymers are typically produced by means of a reaction of a non-degradable glycol prepolymer with cyclohexane diisocyanate. Quay et al does not mention or imply the existence of a biomedical-grade polyurethane; or a polyurethane that has the formula:  $\{A-B-C-B\}_n$ , wherein C denotes a diol component. Quay et al does not teach, either expressly or implicitly that the uniformity of the diol components is such that the length is the same for at least 90% of the diol units. The Examiner in charge of the subject application has previously indicated that the Examples of

Quay et al discloses the use of an excess of diisocyanate which would lead to a homogeneous product. It is respectfully urged that the Quay et al reference does not indicate, either expressly or implicitly, that, as claimed in newly-presented claim 61, the diol unit block length is the same for at least 90% of the diol components.

Furthermore, the "diols" used in the Quay et al reference are "polymers", for example polytetramethylene oxide diol, as set forth in Example 1 at Column 6, line 20. It is commonly known to those having ordinary skill in the art that such a polymer normally does not have a uniform chain length, but has a chain distribution around its average molecular weight. Accordingly, the Quay et al reference is urged to be inapplicable, in that it fails to disclose a polyurethane having any particular level of diol component chain uniformity, let alone a situation wherein at least 90% of the diol components, C, have the same block length.

Nor can the Quay et al reference be applied to reject any of the claims based on obviousness under 35 USC §103(a). The Quay et al reference provides no incentive whatsoever to prepare a biomedical biodegradable polyurethane, let alone prepare one as defined according to newly-presented claim 61, wherein the uniformity is such that at least 90% of the diol units have the same length. Specifically, Quay et al does not suggest in any manner that such a polymer would be particularly suitable for the production of a biocompatible, biodegradable implant with excellent mechanical properties.

With respect to newly-presented claim 62, it is respectfully submitted that the Quay et al 1,4-cyclohexane diisocyanate is different in kind rather than degree from

the 1,4-butane diisocyanate, in creation of the claimed polyurethane. Indeed, nothing in either the Quay et al reference or any other prior art in existence suggests that the 1,4-butane diisocyanate of Applicants' claims can be replaced by the Quay et al 1,4-cyclohexane diisocyanate. It is respectfully pointed out to the Examiner in charge of the above-identified application that the 1,4-butane diisocyanate has an unexpected, unobvious advantage: a polymer containing the 1,4-butane diisocyanate as the diisocyanate moiety is processable into implants without the occurrence of thermal degradation during the implant formation. Furthermore, the solubility of polymers containing the 1,4-butane diisocyanate moieties is significantly greater than the solubility of polymers containing the 1,4-cyclohexane diisocyanate moieties.

With reference to newly-presented claim 63, where C is in the alternative, a butanediol component, a hexane diol component, a diethylene glycol component or a component which is reaction product of the diisocyanate moiety and two molecules of the diol component, Quay et al fails to teach the use of such diols in formation of polymers having the formula:  $(A-B-C-B)_n$ ; whereas Quay et al emphasizes the use of the diol component of a long chain polymer, e.g., polytetramethylene oxide diol. The Examiner's attention is drawn to Column 2, lines 65-69 of the Quay et al reference, to wit:

"The above polyether and polyester diols are conventional for producing polyurethane elastomers and typically they have a molecular weight range of from about 250 to 4,000 and typically from 250 to about 3,000"

Indeed, the diol components of newly-presented claim 63 are particularly suitable in the creation of a biocompatible biodegradable biomedical polymer (of the type needed for implants) with a high degree of uniformity and with excellent mechanical properties. Indeed, the Quay et al reference teaches away from a polyurethane having the diol components specified in newly-presented claim 63, as the Quay et al reference clearly focuses on long chain diols as set forth supra, and as set forth in Examples 1, 6 and 7 of Quay et al. In summary, the Quay et al reference cannot properly be applied in a rejection based on obviousness under 35 USC §103(a).

By the same token, the Quay et al reference cannot properly be applied, on grounds of 35 USC §103(a) obviousness, against newly-presented claim 64. The Quay et al reference fails to disclose or imply a polymer even remotely similar to the polymer defined according to claim 64.

With respect to the 35 USC §103(a) rejections based on the de Groot et al ("New biomedical...") reference, de Groot fails to teach or imply a polyurethane with the uniformity specified in newly-presented claim 61. Indeed, de Groot mentions at page 212 that a diisocyanate-terminated prepolymer is formed using a hydroxyl-terminated poly-ε-caprolactone thusly:

"Polymerization: Diisocyanate terminated prepolymers were prepared by reacting of the hydroxyl terminated poly(ε-caprolactone) in a six fold excess of BDI, HDI or LDI at 80°C for four hours. The excess diisocyanate was removed under reduced pressure..."



Nothing in the de Groot reference indicates that any process variable including use of excess diisocyanate has an effect on the uniformity of the block length of the diol component. Nevertheless, it is commonly known to those having ordinary skill in the art that a polymer does not normally have a uniform length, but has a chain length distribution around its average molecular weight, for example, 2000 in the case of the de Groot poly( $\epsilon$ -caprolactone) as set forth at line 1 of the last paragraph on page 211 of de Groot et al. Thus, the description in the de Groot reference at page 212 of the polymerization does not provide any clue regarding the uniformity of the length of the diol components of the polymer, let alone does this paragraph disclose or infer a uniformity of at least 90%. With respect to the Markush group of diols of newly-presented claim 63, the de Groot reference fails to teach or infer any of the diol components but only discloses the poly( $\epsilon$ -caprolactone).

With reference to claims of the above-identified application, such as newly-presented claim 65 (which replaced claim 37) wherein reference is made to components KXX, YXY and YXYXY, the substance of the relevant argument presented in the amendment of September 4, 2002 is herewith repeated. There is no teaching in the de Groot reference (taken alone or further together with Cohn) providing a polymer wherein the chain extension has been performed as set forth in the claims of the above-identified application. Applicants' process leads to a high degree of uniformity of the diol component which gives rise to the necessary good phase separation and needed excellent mechanical properties of the ultimately-used polymer. There is no teaching in the prior art that the de Groot amine

component, e.g., 1,4-butanediamine can or should be replaced with any of Applicants' diol components. Simply replacing the de Groot diamine with a diol will not necessarily give rise to a polymer having the necessary mechanical properties for construction of implants; as is the case when using Applicants' components of the type: XYX, YXY or YXYXY. This is clearly demonstrated at Table 2, page 10 of the above-identified application where improved physical properties of the polymer containing components of the type: XYX, YXY or YXYXY are indicated.

Nor do the secondary references: de Groot ("Use..."), Cohn, or Gogolewski add anything to the primary de Groot et al reference. The secondary references fail to disclose or infer a polyurethane having the specified uniformity. More particularly, the secondary references are silent regarding the relevance of a uniformity of at least 90% of the diol components for a biocompatible, biodegradable polyurethane having biomedical uses as defined in newly-presented claim 61. In summary, combining the primary de Groot et al reference with the aforesaid secondary references does not provide any teaching of Applicants' invention.

As stated in the amendment filed on September 4, 2002, with respect to the 35 USC §103(a) rejection propounded by the Examiner in charge of the above-identified application, it is respectfully submitted that the following cases support the position of Applicant:

- In re Sembiczak (CA FC, 4/28/99) 50 U.S.P.2d 1614;
- Robotic Vision Systems Inc. vs. View Engineering Inc. (CA FC, 9/1/99) 11 U.S.P.2d 1948;

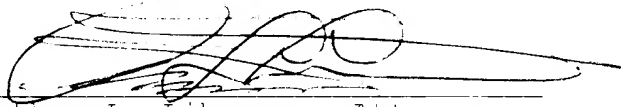
- Aero Industries Inc. vs. John Donovan Enterprises-Florida Inc. (D.Ct.S.Ind., 11/22/99) 53 U.S.P.Q.2d 1547; and
- Winner International Royalty Corp. vs. Wang (CA FC, 1/27/00) 53 U.S.P.Q.2d 1580.

The foregoing amendments and arguments are urged to be fully responsive to the Office Action of May 14, 2002, and, in addition, are urged to place this case in condition for allowance. If the Examiner believes that there are any unresolved issues requiring adverse final action in any of the claims now pending in the application, the Examiner should telephone Mr. Arthur L. Liberman, Esq. at (732) 291-9434 so that appropriate arrangements can be made for resolving such issues as expeditiously as possible.

Accordingly, an early action and allowance of claims #1-85 are respectfully solicited.

Respectfully submitted,

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